Grason-Stadler

GSI® TympStar Version 2

Middle-Ear Analyzer

Quick User Guide

Quick User Guide 2000-0126, Rev 4.0
Printed November, 2003

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GSI
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a division of VIASYS Healthcare

Title: GSI TympStar Version 2
Middle-Ear Analyzer
Quick User Guide

Date: November, 2003

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Part number: 2000-0126

Printing history:				
	March, 2001	First printing	Rev 1.0	
	June, 2002	Second printing	Rev 2.0	
	February, 2003	Third printing	Rev 3.0	
	November, 2003	Fourth printing	Rev 4.0	DCO-0290

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Safety Considerations

General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in these instructions and the rules of the organization using this instrument, the more stringent rules should take precedence.

Conventions used in these instructions

NOTES
Note icons indicate important related information, reminders, recommendations, and suggestions. Notes are shown in bold type.

CAUTIONS
Caution icons indicate information regarding a situation or condition that could result in equipment malfunction or damage, or in lost data. Do not proceed until you thoroughly read and understand the Caution information. Cautions are shown in bold type.

WARNINGS
Warning icons indicate information regarding a situation or condition that could result in personal injury or death. Do not proceed until you thoroughly read and understand the warning information. Warnings are shown in bold type.

Warnings and Cautions

WARNING!

WARNING

The GSI TympStar Middle-Ear Analyzer is designed to be used with a hospital grade outlet. Injury to personnel or damage to equipment can result when a three-prong or two-prong adapter is connected between the GSI TympStar power plug and an AC outlet or extension cord.

WARNING!

WARNING

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- **Use of the ACCESSORY in the PATIENT VICINITY**
- **Evidence that the safety certification of the ACCESSORY has been performed in accordance with the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.**

ANY EQUIPMENT CONNECTED TO THE GSI TYMPSTAR AND USED IN THE PATIENT VICINITY MUST BE POWERED BY AN ISOLATED POWER SOURCE TO MAINTAIN THE ELECTRICAL SAFETY OF THE OVERALL SYSTEM. The isolated power source can be purchased directly from GSI, or elsewhere when approved for use by GSI.

WARNING!

WARNING - ELECTRIC SHOCK HAZARDS

Do not open the case of the TympStar. Refer servicing to qualified personnel.

Do not remove any TympStar covers. Refer servicing to qualified personnel. This includes changing fuses.

WARNING!

WARNINGS - ELECTRICAL GROUNDING

This device uses a three-wire power cord with a hospital grade plug (for international applications, IEC 601-1 approved plug). The chassis is earth grounded. For grounding reliability, connect the device to a hospital grade or hospital only receptacle (for non-U.S. applications, IEC 601-1 approved receptacle). Inspect the power cord often for fraying or other damage. Do not operate the apparatus with a damaged power cord or plug. Improper grounding is a safety hazard.

Do not use extension cords for the TympStar. Extension cords can cause ground integrity and impedance problems.

Periodically check the system ground integrity.

WARNING!

WARNING - EXPLOSION

This system is not explosion proof. Do not use in the presence of flammable anesthetics or other gasses.

WARNING!

WARNINGS - CONNECTIONS

Do not switch on any system power until all cables have been properly connected and verified. See this manual for setup instructions, which accompanies all deliveries of the system.

Switch off the system power before connecting or disconnecting any system component(s) or accessories. Otherwise you may damage the device(s).

WARNING!

WARNINGS - GENERAL

Proper use of this device depends on careful reading of all instructions and labels.

Follow all safety standards set by your place of employment.

Prolonged use of auditory stimuli can cause damage to patient hearing.

CAUTIONS - ELECTRICAL POWER
Electrical Shock Hazard. Do not remove covers. Refer servicing to qualified personnel only.

CAUTION! Make sure your power cord plug is proper for the power outlet into which it will be plugged. i.e., plug in a 120V rated power cord into a 120V outlet only.

TympStar test results data is not stored when the power is turned off. To maintain test results data in the presence of power brown-outs or temporary power interruptions, an Uninterruptable Power Supply (UPS) must be used.

CAUTION - CONNECTIONS
If you disconnect cables, please be careful to reconnect them in their proper locations.

CAUTION!

CAUTIONS - PREVENTIVE MAINTENANCE
Preventative maintenance does not require access to the interior of the instrument and may be performed by the user. For this device, preventative maintenance consists of periodically cleaning and inspecting the exterior of the instrument. Periodic electrical safety testing is recommended. It is recommended a schedule be established for these purposes, with at least an annual cleaning, calibration and safety testing.

CAUTION!

Cleaning consists of removing all dust from the exterior surface of the system with a soft brush or cloth. Use a brush to dislodge any dirt on or around the connectors and panel edges. Remove any dirt with a soft cloth.

CAUTIONS - GENERAL

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Grason-Stadler published specifications. It is recommended that all repairs be performed by a qualified GSI service representative only. You have the sole responsibility for any malfunctions resulting from improper maintenance or repair by anyone other than an authorized GSI representative.

Introduction

CAUTION - SAFE INSTALLATION AND USE
Read all the information in this section to help ensure safe installation and use of the system. As always, follow your institution's safety guidelines when installing, servicing and using the system and any of its components.

Probe tone frequencies available

226 Hz: All Tests
678 Hz: Tymp Diagnostic, Reflex Threshold, Reflex Decay, ETF
1000 Hz: Tymp Diagnostic, Reflex Threshold, ETF.
250 Hz to 2000 Hz Sweep: Multiple Hz.

General

The TympStar Version 2 measures Admittance (Y), and its components:
Susceptance (B)
Conductance (G)
Y and B tracings are highlighted by a bolder display than G.

All Y 226 Hz measurements are labeled in ml of equivalent compliance. All other probe tone and component measurements are labeled in mmhos of admittance.

Tymp tests are automatically scaled. Reflex test scales are selectable using softkeys.

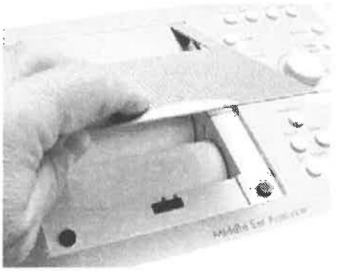
Test data can be ERASED prior to the end of a test (STOP). Up to 26 screens of test data can be stored.

Test data stored in memory can be displayed by pressing PAGE, and deleted by pressing CLEAR.

A cursor is available in all test modes and in PAGE. CURSOR softkeys allow scrolling of cursor to left or right on graphics area. The LCD displays a cursor box that describes the numeric position of the cursor on both the X and Y axes. The cursor may be used to specify and record peak data.

Internal printer

All or only selected screens of test data can be printed. Screens of test data can be printed after each test, or can be selected and printed later. The printer is located under the TympStar front panel. Press the bottom of the printer compartment panel to access the printer paper supply.

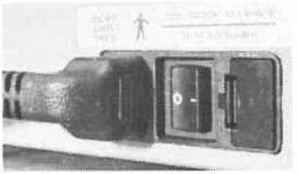


TympStar connections

Connections include power, probe and rear panel accessories.

Power:

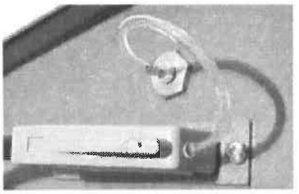
The power cord is plugged into the power switch and fuse module on the left side of the TympStar enclosure.



Probe:

The probe is permanently connected to the right side of the TympStar enclosure. The probe includes:

- Ipsi probe tip and tubing
- Contra insert phone jack



Probe lights indicate the following:

- Solid Green = Test In Progress
- Solid Amber = Occlusion
- Blinking Amber = Leak
- Blinking Green = OK To Begin A Test

CAUTION!

CAUTION

Do not attempt to disconnect the probe electrical cable or pneumatic tubing.

CAUTION!

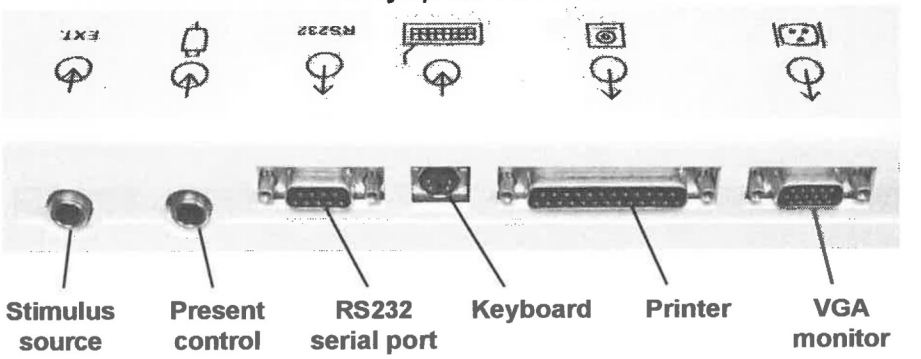
CAUTION

When using the Contra insert phone, ensure that the plug is completely inserted into the phone jack.

Rear panel:

Rear panel connectors include:

- Jack for external stimulus source
- Jack for external stimulus present control
- RS232 serial interface connector



- PS2 computer keyboard connector
- Parallel printer connector
- VGA computer monitor connector

External Keyboard:
An optional external keyboard may be used to enter Patient Name, ID, and Tester Identification.

To enable and utilize this optional feature:

1) Plug the keyboard connector into the rear panel keyboard jack prior to turning the instrument on. A flashing cursor to the right of name on the display is a signal that patient information can be entered via the external keyboard.

2) The Enter key on the keyboard will allow the user to shift to the next line on the display. Left and right arrow keys allow the user to move the cursor left and right on the display. The backspace key allows the user to erase Patient Name, ID, and Tester Information.

3) To clear patient name, ID, and tester once tests are stored in memory, utilize CLEAR ALL in the PAGE mode.

NOTE

NOTE
Clearing individual tests will not clear Patient Name, ID, and Tester Information previously entered using the external keyboard.

LCD contrast control

The contrast adjustment control is located on the right side of the TympStar enclosure.

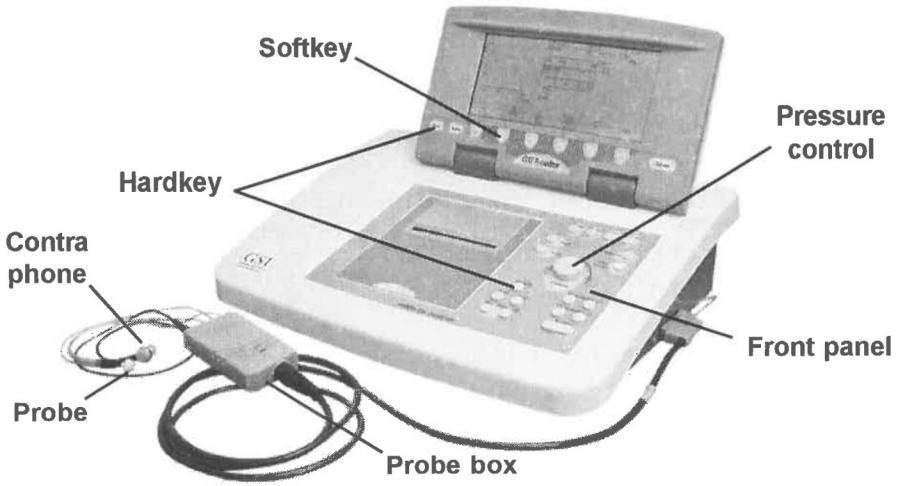
Front panel controls

Front panel controls consist of a pressure control knob and a combination of hardkeys and softkeys.

Pressure control:
Rotary knob used to manually change or fine-tune the pressure within the ear canal.

Softkeys:
Only the six push-buttons located directly under the LCD are softkeys. Their functions are displayed on the LCD and change in support of the current test activities.

Hardkeys:
All of the push-button controls on the front panel are hardkeys. Three hard-keys are also located on the left and right sides of the LCD housing. Their functions are printed directly on the push-button or nearby on the panel and do not change.



Front panel hardkeys:

TYMP:
Causes GSI (or operator programmed) default criteria for diagnostic tymp test to be automatically set up.

REFLEX:
Causes GSI (or operator programmed) default criteria for reflex threshold testing to be automatically set up.

ETF:
Causes GSI (or operator programmed) default criteria for Eustachian tube function (intact eardrum) test to be automatically set up. Also provides path to the Instrument Options area. Press: ETF - RETURN - INSTRUMENT OPTIONS.

SPECIAL:
Causes GSI TympStar to initialize to GSI (or operator programmed) default criteria for reflex decay test.

PAGE:
Allows operator to recall and display tests in memory or in progress.

PRINT:
Allows operator to print selected test results.

REMOTE:
Used when GSI TympStar is interfaced with external computer. Implements a common handshake routine to ensure that the RS232 link is in place.

DATA TRANSFER:
Used to send test data to an external computer.

MANUAL:
Allows the user to run each applicable test procedure manually. The pressure control is used to change pressure manually within the ear canal.

HOLD:
Allows the current test sequence to be temporarily halted without venting the ear canal pressure.

STOP:
Allows the current test sequence to be terminated. The ear canal is vented. Data on the current page is stored in memory.

START:
Causes the selected test sequence to begin in the direction indicated by the associated arrow.

STIMULUS:
Allows available stimuli to be scrolled up or down and selected. This feature is available only for Reflex type tests.

INTENSITY:
Allows operator to select and set desired intensity (dB HL). This feature is available only for Reflex type tests.

PRESENT:
Allows selected stimulus to be presented either manually or according to preset automatic timing. This feature is available only for Reflex type tests.

LCD panel hardkeys:
CLEAR:
Deletes selected tests stored in memory.

ERASE:
Erases current display of test results prior to placing test results in memory.

RETURN:
Allows the operator to go back to next higher level in the softkey menu. Pressing RETURN while in Clear, Page, or Print mode restores the instrument to the mode previously selected.

Instrument Options

The Instrument Options softkey menu can be used to configure a variety of printing, communication, language, test sequence, date and time and other instrument parameters.

To review or reprogram these instrument options, press the ETF hardkey, then the RETURN hardkey.

Press the INSTRUMENT OPTIONS softkey to display the Instrument Options menu.

Test procedures

Tymp diagnostic

1) Select test mode by turning POWER ON, or by pressing TYMP hardkey.
2) Default test parameters are displayed above softkeys on the LCD.
   A) Selectable Probe Tone Hz: 226, 678, 1000
   B) Selectable Admittance Components: Y, B, G, B/G
3) Temporarily modify test parameters, if desired, by pressing parameter softkey(s) to be changed. Use PROGRAM mode for more permanent changes.
   A) Alternative test parameters are displayed above selected softkey.
   B) Press desired test parameter softkey. Selected value is displayed on parameter status line.
   C) Press BASELINE-OFF if tymp test is performed with the following parameters:
      - Y with 678 Hz or 1000 Hz
      - B, G, or B/G with 226 Hz, 678 Hz, or 1000 Hz

NOTE
Pressing B/G softkey allows B and G tracings to be run simultaneously.

4) Attach probe box to velcro strip on shoulder probe mount.
5) Position shoulder probe mount on patient.
6) Position appropriate size eartip on probe tip and securely insert in ear canal.
7) Press EAR softkey, then press LEFT or RIGHT ear.
8) Press ◄— START to initiate test.
9) View ongoing test results on graphic display area, and on pressure and admittance meters.
10) For tymp tests other than Y 226 Hz, the cursor is used to identify and set peak data points as follows:
    A) Press CURSOR softkey.

B) Use arrow softkeys to move cursor to left or right on graphics area. Observe numeric data in cursor box at the right of pressure meter.

C) Press TYMP 1 SET PEAK softkey to specify and store peak data for TYMP 1. Follow same procedure to specify and store selected peak data for TYMP 2 and 3, if appropriate.

D) Press CURSOR-OFF.

11) Press STOP to end the test, store the results in memory, and display the summary data on the screen.

NOTE

A manual tymp test may be initiated by pressing MANUAL hardkey. Rotate the pressure knob to vary pressure and view ongoing test results graphically, or on pressure and admittance meters.

Manual tymp

1) Securely insert the probe tip within the patient's ear canal and press the TYMP hardkey.
2) Press the EAR softkey and select the right or left ear.
3) Press the MANUAL hardkey to pressurize the ear canal to the previously selected start pressure. Manual mode will appear below the Name, ID and Tester Information on the display.
4) Use the PRESSURE CONTROL knob to vary the pressure within the ear canal and control the speed of the tympanometric test.
5) View test results on the display along with the pressure and compliance meters. Test summary information is displayed to the right of the meters for the two most recent pressure sweeps.

NOTE
The ERASE hardkey can be used to delete test data prior to pressing the STOP hardkey.

6) Press the STOP hardkey to store the last two tracings in memory.
7) Press the PAGE hardkey to view test results.
8) Press the PRINT hardkey while in the PAGE mode for printed tests. MANUAL will appear on the printout indicating a manual test.

Tymp screening

1) Enter test mode by pressing TYMP followed by RETURN. Press SCREEN softkey. Test will automatically start once seal is detected.
2) Default test parameters are displayed above softkeys on the LCD. Only 226 Hz Y is available in this test mode.
3) Attach probe box to velcro strip on shoulder probe mount or to wristband probe mount.
4) Press EAR softkey, then press LEFT or RIGHT ear.
5) Position appropriate size SCREENING eartip on probe tip.
6) With hand-held probe, obtain seal at entrance to ear canal.

Probe lights indicate the following:

Solid Green = Test In Progress
Solid Amber = Occlusion
Blinking Amber = Leak
Blinking Green = OK To Begin A Test

7) Test will start automatically if ear canal seal is good. Screening IPSI Reflex test at 1 kHz will follow tymp.
8) A "Test Complete Remove Probe" message will appear on the display when the test is complete.
9) View test results on graphic display area along with summary data at the right of the pressure and compliance meters.

Reflex threshold

1) Select test mode by pressing REFLEX.
2) Default test parameters are displayed above softkeys on the LCD.
   A) Selectable Probe Tone Frequencies: 226 Hz, 678 Hz, 1000 Hz.
   B) Selectable Admittance Components: Y, B, G
   C) AUTO ZERO is used to baseline admittance between stimulus presentations.

NOTE
Reflex responses may be inverted, or deflected in an upward direction when using higher probe tones. Direction of response may also differ when testing with Y, B or G components.

   D) Alternative sensitivities for displayed reflex response may be selected by pressing ml SCALE softkey.
3) Press START to pressurize ear to dynamic peak pressure maintained from last tymp, or to 0 daPa if no previous tymp data is available. Pressure control is active for fine-tuning pressure if tymp is sharply sloped, i.e.: offset from peak by 10 to 15 daPa.
4) Select intensity of stimulus by pressing INTENSITY up or down arrow. Press STEP SIZE softkey to set 1, 2, or 5 dB steps.
5) Present auto-timed stimulus by momentarily pressing PRESENT bar. (Stimulus may also be presented with manual timing.)
6) Press ERASE to erase sub-threshold presentations or unwanted data, i.e.: amplitudes of less than 0.02 ml with 226 Hz, 0.06 mmhos with 678 Hz, or 0.09 mmhos with 1000 Hz.
7) Press CONTINUE softkey to allow reflex tracings to continue onto next line of reflex screen and onto the next page in memory.

NOTE
Once CONTINUE is selected, test results are stored in memory and may not be erased.

8) The STIMULUS up and down arrow hardkeys are used to select alternative test stimuli.

9) CURSOR softkey may be used to examine data points from individual tracings.
10) If Reflex Decay, ARLT, or AR Sensitization testing is to be done on same ear, press SPECIAL hardkey without pressing STOP. This allows pressure from Reflex Threshold to be maintained for next test. If not, press STOP to terminate testing.

Automatic auto zero

Auto Zero is used to baseline admittance prior to or between stimulus presentations when performing acoustic Reflex Threshold, Reflex Decay, Acoustic Reflex Latency and Acoustic Reflex Sensitization tests.

Before pressing START, select the AUTO ZERO softkey followed by the AUTOMATIC softkey to activate this feature. The Admittance meter will automatically be zeroed each time the PRESENT bar is pressed.

The Admittance meter may be zeroed manually after pressing START by pressing the AUTO ZERO softkey as frequently as needed.

Mark Threshold:

Often multiple tracings are obtained per stimulus presentation, but only one represents the reflex threshold. Mark Threshold allows the operator to scroll across each line of data and select the intensity values determined to be the threshold.

1) Select the MARK THRESHOLD soft key.
2) Select the → soft key to move the cursor.
3) Press the MARK LINE 1 or MARK LINE 2 softkey to display the threshold marker (an asterisk).
4) Press the NR LINE 1 or NR LINE 2 softkey to display no response (NR).
5) Select EXIT soft key to return to the reflex threshold diagnostic menu.

Reflex Threshold Seeking:

Threshold Seek automates the sequence of button presses used to arrive at reflex threshold values and also automates the marking of reflex threshold values.

NOTE
Threshold Seek should only be used with quiet, cooperative patients.

1) Select test mode by depressing REFLEX. Default test parameters are displayed above soft keys on the LCD.
2) Press THRESHOLD SEEK soft key.
3) Press ON or CONFIGURE to change test parameters.
4) Press START to pressure ear to dynamic peak pressure maintained from last tymp, or to 0 dapa if no previous tymp data is available.
5) Present auto timed stimulus by momentarily depressing the PRESENT bar.
6) Press ERASE to erase unwanted data.
7) Select CONTINUE soft key to allow reflex tracing to continue on the next line on the reflex screen.

NOTE
MANUAL REFLEX testing may be performed by pressing MANUAL and viewing responses to stimuli presentations on the compliance meter.

Reflex decay

1) Select test mode by pressing SPECIAL.
2) Default test parameters are displayed above softkeys on the LCD.
   A) Selectable Probe Tone Frequencies: 226 Hz, 678 Hz.
   B) Selectable Admittance Components: Y, B, G
   C) Alternative sensitivities for displayed reflex response may be selected by pressing ml SCALE softkey.
   D) Maximum selectable stimulus ON TIME is limited by selected TIMEBASE.
   E) AUTO ZERO is used to baseline admittance between stimulus presentations.
3) Dotted vertical lines indicate 5 sec. and 10 sec. points.
4) Pressure control is active for fine-tuning pressure.
5) Set intensity of stimulus to 10 dB above reflex threshold by pressing INTENSITY up or down arrows. Step size may be set to 1, 2, or 5 dB using STEP SIZE softkey.
6) Present stimulus by pressing PRESENT bar momentarily. First press START if pressure was not maintained from a prior reflex test.

NOTE

Summary data indicates time at which 50% decay occurred, if appropriate. CURSOR softkeys may be used to call out numeric points on Line 1 and Line 2 of the graphics area.

7) Additional frequencies may be tested by using the STIMULUS up and down arrow hardkeys. (500 Hz and 1000 Hz are the best frequencies for this test.)
8) Go directly to another reflex test without pressing STOP to maintain pressure within ear canal, or press STOP to terminate reflex decay testing.

Acoustic reflex latency test (ARLT)

1) Press SPECIAL followed by RETURN.
2) Select test mode by pressing ARLT softkey. Default test parameters are displayed above softkeys on the LCD.
   A) ARLT is performed with a 226 Hz Probe Tone. Y, B or G may be selected.
   B) Maximum selectable ON TIME of the stimulus is limited by selected TIMEBASE.
   C) Alternative sensitivities for displayed reflex response may be selected by pressing ml SCALE softkey.
   D) Press AVERAGE softkey to change number of reflex responses to be averaged.
3) Pressure knob is active for fine-tuning pressure.
4) Set intensity of stimulus to 10 dB above reflex threshold by pressing INTENSITY up and down arrows. Step size may be set to 1, 2, or 5 dB using STEP SIZE softkey.
5) Use AUTO ZERO, if necessary, to zero admittance prior to presenting stimulus.
6) Present stimulus by pressing PRESENT bar momentarily. First press START if pressure was not maintained from a prior reflex test.
7) The following points are identified by short vertical lines on the ARLT display:
   A) Time from signal onset to points where reflex curve reaches 10% and 90% of its maximum amplitude.
   B) Time from signal offset to points where reflex curve decays to 90% and 10% of its maximum amplitude.

NOTE
Numeric summary data indicates the 10%/90% ON and OFF points of the response for Line 1 and Line 2. CURSOR softkeys may be used to call out numeric points on X and Y axes of Line 1 and 2.

8) Additional frequencies may be tested by using STIMULUS up and down arrow hardkeys.
9) Go directly to another reflex test without pressing STOP to maintain pressure within the ear canal, or press STOP to terminate ARLT testing.

Acoustic reflex sensitization (A.R. SENSI)

1) Press SPECIAL followed by RETURN.
2) Select test mode by pressing A.R. SENSI softkey. Default test parameters are displayed above softkeys on the LCD. Test is performed with a 226 Hz probe tone. Y, B, or G may be selected.

NOTE
The facilitator (sensitizing signal) threshold level should be known prior to selecting the facilitator parameters. (6 kHz or BBN are most suited for facilitator stimuli.)

3) Press STIMULUS EAR softkey and press IPSI or CONTRA to obtain reflex threshold data if threshold information per stimulus has not already been obtained. Use same procedure as in Reflex Threshold.
   A) IPSI stimuli available: 0.5, 1, 2, 4, 6 kHz, EXT, and N-A.
   B) CONTRA stimuli available: 0.25,0.5,l, 2,4,6 kHz, BBN, EXT, and N-A.

NOTE
STEP SIZE should be set to 1 or 2 dB to obtain precise threshold data.

4) The facilitating (f) and activating (a) stimuli may be presented IPSI (I) or CONTRA (C). Use the STIMULUS EAR softkey to press the desired combination: CfIa, CfCa, IfCa, Ifia.
5) To select the facilitator stimulus and intensity, press the FACILITATOR softkey.
   A) Use the STIMULUS up and down arrows to select the desired high frequency stimulus.
   B) Use the INTENSITY up and down arrows to set intensity level. Try 3 to 4 dB below threshold level for selected stimulus.
   C) Press EXIT.

6) The activator stimulus and intensity may now be selected.
   A) Use the STIMULUS up and down arrows to select desired stimulus.
   B) Press STEP SIZE softkey to select 1, 2, or 5 dB steps.

C) Use the INTENSITY up and down arrows to set dB level. Start intensity of activator at a very low level, e.g.: 40 dB to arrive at thresh old value.
   - IPSI Stimuli available: 0.5, 1, 2, 4 kHz, EXT, and N-A.
   - CONTRA Stimuli available: 0.25,0.5,l, 2,4 kHz, BBN, EXT, and N-A.

7) Press PRESENT to simultaneously present facilitating and activating stimuli. First press START if pressure was not maintained from a prior reflex test.
8) Press ERASE to delete sub-threshold presentations or unwanted data, i.e.: amplitudes below 0.02 ml.
9) Press STOP to terminate testing.

Eustachian tube function

Pressure Swallow Test (intact TM)

1) Select test mode by pressing ETF. Default test parameters for ETF-INTACT TM are displayed above softkeys on the LCD.
2) Press ◄— START to initiate automated test (TYMP 1).
3) View ongoing test results as shown on graphic display area, or pressure compliance admittance meters.
4) Press HOLD when desired pressure sweep limit is reached.
5) Follow user directions displayed on status line of LCD prior to obtaining TYMP 2 results using CONTINUE softkey.
6) Press HOLD when desired pressure sweep limit for TYMP 2 is reached.
7) Follow user directions displayed on status line of LCD prior to obtaining TYMP 3 results using CONTINUE softkey.
8) Press STOP when desired pressure sweep limit for TYMP 3 is reached.
9) If Eustachian tube is functioning properly, view shift in pressure peaks of TYMPS 2 and 3 relative to TYMP 1 on graphic display area. Numeric summary data is displayed at the right of compliance/admittance meter.

Perforated Ear Test (Perforated TM)

1) Select ETF-Perforated TM by pressing ETF (if not already pressed) and RETURN followed by PERF TM softkey.
2) Position eartip within ear canal.
3) Press START to initiate pressure sweep.
4) If Eustachian tube opens during pressurization, the opening and closing pressures will be indicated in the summary data.
5) If the Eustachian tube doesn't open during pressurization, instruct the patient to swallow some water. The opening and closing pressures will be indicated.
6) Press STOP to end the test and store the results in memory.

Multiple frequency tympanometry (MULTIPLE Hz)

1) Press CLEAR. Press CLEAR ALL softkey to ensure the availability of 26 pages of memory.
2) Press SPECIAL followed by RETURN.
3) Select test mode by pressing MULTIPLE Hz softkey. Default test parameters for TEST 1 of the test series are displayed above softkeys on the LCD.
   A) The GSI TympStar automatically runs a 226 Hz Y tymp to determine the peak pressure value for the second probe frequency sweep.
   B) The ADMITTANCE softkey indicates which component is measured as a function of probe frequency at the start and peak pressures. (B is the best component for this test.)

NOTE
It may be helpful to select a sweep rate of 12.5 daPa/ sec for sharply sloped tymps.

4) Ensure that the ear canal is securely sealed.
5) Press ◄— START to initiate test. Probe tone automatically sweeps from 250 Hz to 2000 Hz in 50 Hz steps at start pressure.
6) Next, Y 226 Hz tymp data is collected and displayed as TEST 1 of the series. As in Tymp Diagnostic Mode, press HOLD at desired stopping pressure or allow pressure sweep to continue to -400 daPa.
   A) Tymp summary data will be displayed at the right of the admittance meter.
   B) Use CURSOR if a different peak pressure value is desired.
7) Press CONTINUE softkey to initiate TEST 2 of the series. Probe tone automatically sweeps from 250 Hz to 2000 Hz in 50 Hz steps at tymp peak pressure.
8) ΔB (or ΔY, or ΔG, if selected) are calculated and plotted as a function of probe frequency on upper graph display. Changes in phase of admittance ($\Delta\theta$) as a function of probe frequency are calculated and plotted on the lower graph.

NOTE

ΔY, B, or G values and Δθ values are calculated as the difference between values obtained at peak pressure versus start pressure.

9) A cursor line approximates the resonance point of the ear along Hz axis.
   A) CURSOR left and right arrow softkeys may be used to specify a different Hz point for ΔY, B, or G values and Δθ . Press SET Hz softkey to record new value.
   B) Cursor position now determines probe frequency for next tymp.
10) Press CONTINUE to display tymp format for TEST 3 of the series.
11) Press START or CONTINUE to obtain a tymp at this probe frequency.
   A) Tymp data is displayed on screen for selected probe frequency.
   B) Use CURSOR left and right arrow softkeys to specify and set peak admittance and pressure.
12) Test sequence can be terminated by selecting STOP,
   OR
13) Tymps can be obtained for frequencies below and above identified resonance point of the ear. To select probe tone frequency for next tymp:
   A) Press PROBE Hz softkey. Use up and down arrows to arrive at desired Hz. Press SET Hz softkey to select probe tone. Use ⟵ START or CONTINUE to run next tymp.
   OR
   B) Press DELTA DISPLAY softkey to return to delta display screen. Cursor line indicates probe frequency from last tymp. Press CURSOR to select new probe tone frequency. Press CONTINUE followed by ⟵ START or CONTINUE to begin next tymp.
14) Press STOP to end the test.

Auto sequence testing

1) Press the TYMP hardkey to place the instrument in the tymp diagnostic mode.
2) Press the EAR softkey to select the test ear.
3) Select AUTO SEQUENCE softkey to initiate the automatic sequencing of tests.
4) The test sequence will automatically terminate upon completion of the last test with test results automatically stored in memory.
5) Test results can be viewed by pressing the PAGE hardkey and can then be printed by pressing the PRINT hardkey.

NOTE
The sequence of tests always includes Tymp 226 Hz, Y, and can be configured to include or exclude Reflex Threshold and Reflex Decay tests.

Programming auto sequence tests

1) Select the ETF hardkey followed by the RETURN hardkey.
2) Select the INSTRUMENT OPTIONS softkey and then press the TEST SEQUENCE softkey.
3) Select REFLEX THRESHOLD softkey and press the ON/OFF softkey to activate or deactivate reflex threshold.
4) Acoustic reflex measurements can be obtained ipsilaterally or contralaterally. Select the STIMULUS EAR softkey to choose from Ipsi only, Contra only, or Ipsi and Contra for reflex testing.
5) Press the STIMULUS Hz softkey to select the stimulus to be included in the Reflex Threshold Auto Sequence. Scroll through each stimulus by pressing the up and down arrow softkeys to scroll through the stimuli and toggle the YES/NO softkey to program each stimulus for Reflex Threshold testing in the auto test sequence.
6) Select the REFLEX DECAY softkey and press the ON/OFF softkey to activate or deactivate reflex decay.
7) Select the STIMULUS Hz softkey to select the stimuli for Reflex Decay testing. Press the up and down arrow softkeys to scroll through the stimuli and toggle the YES/NO softkey to select or deselect the stimulus.
8) Press the RETURN hardkey twice and press the STORE softkey to store test selections in memory.

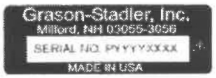
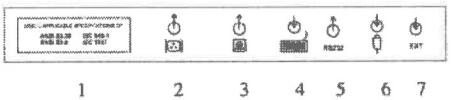
Appendix A

Additional Information

TympStar Labels

Following are the labels used on the TympStar Middle Ear Analyzer instrument. Match the labels shown to the labels affixed to your system.

Part Number	Label	Comments
1707-0403	CAUTION ELECTRIC SHOCK HAZARD, DO NOT REMOVE COVER. REFER SERVICING TO QUALIFIED PERSONNEL.	To guard against serious injury or instrument damage, do not remove the cover. Have the unit repaired by qualified personnel.
1770-0403	CLASSIFIED UL 2601-1 CAN/CSA C22.2 No. 601.1 MEDICAL EQUIPMENT 24GA CLASSIFIED C UL CE 0050	United States and International standards approvals.
2000-0408	LCD CONTRAST	The contrast control for the Liquid Crystal Display (LCD).
2000-0409	PAPER LOADING INSERT THE LEADING EDGE SQUARELY INTO THE PAPER ENTRANCE. ORIENT ROLL AS SHOWN: TO PRINTER	Load the printer paper as shown in the diagram.
2000-2000	Grason-Stadler, Inc. Milford, NH 03055-3056 REF NO. 2005-97XX SERIAL NO. YYYYXXXX MADE IN USA	Unit serial number label

2000-3200		Probe serial number label
2000-0419		Version 1 probe part number identification.
2000-0432		Version 2 probe part number identification
2000-7002		Symbol 1: Attention, consult accompanying documents. Number 2: This is not a symbol, it is a hole for a screw. Symbol 3: Dangerous voltage.
2000-0420		Clear, Erase and Return keys. Six "soft keys", or keys which change function by software control.
2000-0445		Symbol 1: The TympStar meets the applicable specifications of the listed industry standards. Symbol 2: External VGA monitor output. Symbol 3: External printer output. Symbol 4: PC keyboard input. Symbol 5: RS232 serial input. Symbol 6: External PRESENT input (V2 instruments only). Symbol 7: External stimulus signal input (V2 instruments only).
2000-0433		Text 1: specifies the medical device type according to international standard IEC601-1. Symbol 2: Type B equipment Text 3: Input AC power range and fuse type.

European Authorized Representative

The European Authorized Representative for this product is:

Nicolet-EME GmbH
Kleinostheim, Germany

Specifications for your system

TympStar system specifications are listed in the Reference Instruction Manual supplied with your system.

Restricted environmental conditions for operation, transport and storage

CAUTION

The following information is applicable to your system unless otherwise noted. This information is subject to change without notice.

Temperature:
Storage and shipping: -40 degrees C to +75 degrees C
Operating: +15 degrees C to + 35 degrees C
Humidity: 90% at 35 degrees C (non-condensing)
Altitude (operating): 0 - 6000 feet (0 - 1800 meters)

Protective packaging measures

This equipment is designed for normal medical use. For storage and transportation, additional protection from environmental conditions and handling is recommended. Protect from condensation and impact.

Accuracy

Display accuracy at 226 Hz: 0.1 ml or 5%, whichever is greater
Display accuracy above 226 Hz probe signal: (F/226) x 0.1 mmho or K% whichever is greater.
K FACTOR: From 250 to 1500 Hz = 5%; above 1500 Hz = 10%.
Probe signal frequency accuracy:
Discrete and sweep: +/-1%
From 250 to 1000 Hz: +/-1%
Above 1000 Hz: +/-2%

Probe signal level accuracy:

226 Hz:	+/-1.5 dB SPL
Other frequencies:	+/-3.0 dB SPL

Pressure accuracy: +/-10% or +/-10 daPa, whichever is greater in cavities from 0.5cc to 5.0cc.

Pressure sweep rate accuracy: +/-10%

Pure tone stimulus frequency accuracy: +/-3%

Click stimulus rate accuracy: +/-1 pulse/sec

NOTES

NOTES

GSI
Grason-Stadler
a division of
VIASYS Healthcare